

EFFICACY EVALUATION & SCIENCE SUPPORT BRANCH
ANTIMICROBIAL DIVISION

Date In: 04-24-98 Date Out: 06-12-98

EPA Received Date: 03-02-98

RASSB Received Data: 04-01-98

Reviewed by: Bruce H. Mann Microbiologist

Lan Code: 54289-4.698

EPA Reg. No. or File Symbol 54289-U

Product Name Paraclean R 15% (Peroxyacetic Acid Solution)

Product Type Hospital Disinfectant, General Disinfectant, and a Sanitizer (for food contact surfaces).

Company Name Degussa Corporation

MRID No (s): 445059-02, -03, and -04.

Product Manager/Reviewer & Team No.: Swindell/Terry PM-33

Submission Purpose: A new application. The product is reported to be similar or identical to EPA Reg. No. 68660-3, EPA Reg. No 1677-129 and EPA Reg. No. 65402-2

Product Formulation A liquid concentrate to be diluted for use.

ACTIVE INGREDIENT (S)	%
Hydrogen peroxide	22.00
Peroxyacetic acid	15.00

200.0 Introduction

200.1 Use (s)

Refer to the attached labeling which is proposed as Peraclean R 15% (Peroxyacetic Acid Solution), dated 03-02-98.

200.2 Background Information

The current submission is a new application which includes basic efficacy data in support of a hospital claim, in support of a sanitizing data for food contact surfaces and fungicidal data in support of a fungicidal claim. Also, the product proposed label has been submitted in support of this application. The proposed application is reported to be similar or identical to products #1677-129, #65402-2 and #68660-3.

Additional test microorganisms are also included with the proposed submission.

All data reports and label comments are summarized below.

201.0 DATA SUMMARY

201.1 BRIEF DESCRIPTION OF TESTS

Efficacy Reports were developed by ViroMed Laboratories, Inc., 6101 Blue Circle Drive, Minneapolis, MN 55343.

- A. Disinfection (Required Test Bacteria and Additional Tests Microorganisms) were developed in the presence of 5% fetal bovine serum and 400 ppm of synthetic hard water. Data were developed by the AOAC Use Dilution Test method, 15th edition, 1990. Report #3504, experimental start date 04-22-97, completion 06-09-97.
- B. Sanitization of Food Contact Surfaces (Required Test Microorganisms) were developed in 400 ppm of synthetic hard water. Data were developed by the AOAC Germicidal and Detergent Sanitizing Action Test Method of the AOAC, 15th edition, 1990. Report # 3500, experimental start date 04-23-97,

date 06-04-97.

- C. Disinfection (Required Test Bacteria-Fungicidal Data)
were developed in the presence of 5% fetal bovine serum
and 400 ppm of synthetic hard water by the Fungicidal
Activity Test Method of the AOAC, 15th edition, 1990.
Report #3498, experimental start date 04-10-97, completion
date 04-28-97

201.2 Test summaries, refer to the recommendations under Part II,
and see 202.1 (a) (b) (c).